Eric I. Abraham
William P. Murtha
HILL WALLACK LLP
21 Roszel Road
P.O. Box 5226
Princeton, NJ 08543
(609) 924-0808
eabraham@hillwallack.com

Attorneys for Defendants eVenus Pharmaceuticals Laboratories, Inc., Jiangsu Hengrui Pharmaceuticals Co., Ltd., and Fresenius Kabi USA, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PACIRA PHARMACEUTICALS, INC., and PACIRA BIOSCIENCES, INC.,
Plaintiffs,
v.
eVenus PHARMACEUTICALS LABORATORIES, INC., JIANGSU HENGRUI PHARMACEUTICALS CO., LTD., and FRESENIUS KABI USA, LLC,
Defendants.

Civil Action No. 2:21-cv-19829
Civil Action No. 2:22-cv-00718
(consolidated)

Assigned to:
Judge Madeline Cox Arleo
Magistrate Judge Jose R. Almonte

DEFENDANTS' PROPOSED SUPPLEMENTAL FINDINGS OF FACT AND CONCLUSIONS OF LAW

Pursuant to the Court's Order (ECF No. 393), Defendants submit the following proposed supplemental findings of fact and conclusions of law.

1. Pacira has provided no evidence that Jiangsu Hengrui (or any Defendant) failed to produce, or destroyed, any documents relating to the bupivacaine liposome injectable suspension products that are subject to ANDA No. 214348 at issue in this case. While the FDA issued a Form 483 Notice (PTX-494)[1] to Jiangsu Hengrui on January 16, 2024, that Notice concerned a facility (Huanghe Road) that is clearly not involved in the manufacture or testing of bupivacaine liposome injectable suspension products that are subject to ANDA No. 214348. Rather, as required by the FDA, ANDA No. 214348 explicitly discloses all facilities involved in the manufacture and testing of the bupivacaine liposome injectable suspension products that are subject to that ANDA; the Huanghe Road facility subject to the Form 483 Notice is not one of them. DTX-3119.[2] Furthermore, after the FDA issued the Form 483 Notice, it gave final approval to Jiangsu Hengrui's bupivacaine liposome injectable suspension products that are subject to ANDA No. 214348;[3] this supports that the FDA has no outstanding issues with ANDA No. 214348 or the documentation related to it.

[1] Defendants object to the admission of PTX-494 as irrelevant and prejudicial, as it relates to a facility that had no involvement with the bupivacaine liposome injectable suspension products that are subject to ANDA No. 214348.

[2] Jiangsu Hengrui requests that DTX-3119 be provisionally maintained under seal, subject to a forthcoming motion to seal, as it contains Jiangsu Hengrui's confidential information relating to the manufacture and testing of the bupivacaine liposome injectable suspension products that are subject to ANDA No. 214348.

[3] Pursuant to Federal Rule of Evidence 201(b)(2), the Court may take judicial notice of the FDA's approval of Jiangsu Hengrui's ANDA No. 214348. *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=214348 (FDA website, indicating FDA approval of ANDA No. 214348 on July 1, 2024).

2. The trial record includes results of Jiangsu Hengrui's testing of EXPAREL® under accelerated stability conditions at 25 ºC for six months. JTX-4026.0018. Pacira was not prevented from cross-examining Dr. Schwendeman concerning this data. At trial, Pacira's counsel chose not to question Dr. Schwendeman regarding the data.

3. The information that Pacira claims was not produced or might have been destroyed—test results from testing of EXPAREL® under accelerated stability conditions—would not be inconsistent with Defendants' invalidity arguments. The flawed logic behind Pacira's assertion is that Defendants' invalidity position would be undermined if there was any evidence that a prior art batch of EXPAREL® does not practice asserted claim 7 of the '495 Patent. The Court concludes that the sale of a single anticipating batch would render claim 7 anticipated and the evidence, as a whole, presented at trial demonstrated by clear and convincing evidence that one or more of Pacira's approximately 2,600 batches sold before January 2021 anticipated claim 7. ECF No. 365-1 (Defendants' Proposed Findings of Fact) at ¶¶ 135-148; ECF No. 365 (Defendants' Post-Trial Opening Brief on Invalidity and Unenforceability) at 28-35; *Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co.*, 417 F.3d 1203, 1209 (Fed. Cir. 2005) ("We need not consider whether the district court was correct as to all of these sales because a single sale or offer for sale suffices to bar patentability."). In light of the evidence submitted at trial (that some batches met the six-month erucic acid concentration limitation of claim 7, while others did not), the stability test results about which Pacira now speculates would not have been inconsistent with any argument presented at trial.

Dated: July 25, 2024

Respectfully submitted,

/s/ Eric Abraham

Eric I. Abraham
William P. Murtha
HILL WALLACK LLP
21 Roszel Road
P.O. Box 5226
Princeton, NJ 08543
(609) 924-0808
eabraham@hillwallack.com
wmurtha@hillwallack.com

Attorneys for Defendants eVenus Pharmaceuticals Laboratories, Inc., Jiangsu Hengrui Pharmaceuticals Co., Ltd., and Fresenius Kabi USA, LLC

OF COUNSEL:
Daryl L. Wiesen
Kevin J. DeJong
Kathleen A. McGuinness
Andrew S. McDonough
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000
dwiesen@goodwinlaw.com
kdejong@goodwinlaw.com
kmcguinness@goodwinlaw.com
amcdonough@goodwinlaw.com

Alison Siedor
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, DC 20036
(202) 346-4000
asiedor@goodwinlaw.com